REMARKS

Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,077,527. The examiner urges that the claims of the instant application and the issued patent are not patentably distinct since both claim an adhesive composition comprising alkyl acrylate monomer and/or alkyl methacrylate monomer and nitrogen containing monomer.

Claims 1-14 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over any of over U.S. Patent Application Publication No. 2002/0150613 ('613), Patent 6,132,760 ('760) or by U.S. Patent 6,077,527 ('527).

U.S. Patent '527 is cited by the examiner as disclosing a pressure sensitive adhesive composition for use in transdermal drug delivery devices comprising at least 40 % by weight of alkyl acrylate including n-butyl and 2-ethylhexyl acrylate, and 10-60% by weight of substituted acrylamide, or (meth)acrylamide including t-octyl acrylamide. The examiner urges that applicants' claimed Tg is inherent for the particular composition.

The '613 document is cited by the examiner as disclosing a transdermal drug delivery device comprising a backing layer, a release liner and an adhesive layer comprising the drug, the adhesive layer comprising 40-90 % by weight of alkyl acrylate including n-butyl acrylate and 2-ethyhexyl acrylate and 15-30% by weight of monomer selected from (meth)acrylamide, N-butyl-acrylamide or (meth)acrylonitrile. The examiner urges that applicants' claimed Tg is inherent for the particular composition.

The '760 patent is cited by the examiner as disclosing a transdermal drug delivery device including an adhesive layer containing an active ingredient, a backing layer and a release liner. The adhesive layer comprising 45-95 % by weight of alkyl acrylate including n-butyl acrylate, 2-ethylhexyl acrylate and methacrylate and 5-55% by weight of substituted acrylamide, acrylonitrile, (meth)acrylonitrile and vinyl acetamide. The examiner urges that applicants' claimed Tg is inherent

for the particular composition.

The examiner urges that while '613 and '760 do not teach the species of acrylamide (t-octyl acrylamide) and '527 does not teach the backing layer or release liner of the transdermal device, it is within the skill of the art to replace one species by another or genus by species known to perform similar functions. In particular, the examiner urges that it would have been obvious to replace the substituted acrylamide of '613 or '760 by t-octyl acrylamide. The examiner further urges that no criticality has been shown in using t-octyl acrylamide in particular.

arguments

Applicants submit that the claimed subject matter would not have been obvious to the skilled practitioner from any of the cited '527, '613, or '760 documents

None of the '527, '613, or '760 documents disclosure or even suggests an adhesive useful in transdermal drug delivery systems lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. There is nothing in the '613, '760 or '527 disclosure that would motivate the skilled artisan to select the components required for use in the practice of applicants' claimed invention.

The '527 patent does not disclose an adhesive composition that lacks functional groups containing reactive hydrogen moieties and contains no post-polymerization chemical crosslinker. The examiner is referred to col. 2, lines 49-50, wherein use of acrylic acid and vinyl monomers such as vinyl acetate, which contain functional groups, are described for use. See also col. 4, lines 17-27. Moreover, the '527 patent requires the use of a crosslinker (see col. 4, lines 28-31) that cannot be used in the practice of applicants' invention. In order to use the aluminum or titanium crosslinker described in the '527 patent, acrylic monomers that contain a reactive group are needed. The disclosure of the '527 patent is concerned with problems associated with use of penetration enhancers in adhesives used in transdermal systems, and is directed to adhesives tolerant to plasticization by penetration enhancers used in transdermal systems. In contrast, applicants' invention is concerned with problems associated with the reactivity of drugs with adhesives used in transdermal systems, and is directed to non-reactive adhesives, i.e., adhesives that do not contain a reactive hydrogen or any post-polymerization chemical crosslinking.

The examiner argues that the adhesive composition disclosed in the '527 patent is the same as applicants', and refers to the structural formulae in col. 2 and 3 as lacking reactive functional groups. In response, applicants note that the '527 adhesive requires not only component (iii) but also other components as well, components that required a reactive hydrogen. In all examples, a reactive hydrogen is present, and crosslinker is also present. Claim 1 requires the presence of a crosslinker and, as such, a reactive hydrogen must be present, e.g., either as component (ii) or component (iv). See also claim 7. The '527 patents provides no teaching that would suggest applicants invention or motivate the skilled artisan to prepare the adhesives claimed by applicants.

Applicants submit that the claimed invention would not be obvious from the '527 disclosure. Withdrawal of the Section 103 rejection and obviousness-type double patenting rejection based on '527 is requested.

The '613 disclosure is concerned with adhesives for use with highly plasticizing drugs. The described adhesives contain between about 1% and about 15% by weight of a functionalizing monomer which facilitates crosslinking and may include a crosslinking agent (see paragraph [0024], lines 10-12). The examiner is also referred to paragraph [0028].

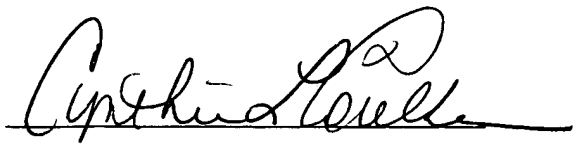
The '760 patent is directed to a transdermal device for the delivery of testosterone. Preferred adhesives are acrylate copolymers comprising one or more A monomers and one or more B monomers (see col. 2, lines 47-48 to col. 3, lines 1- 28). Suitable B monomers include those comprising a functional group. Exemplified monomers include, e.g., acrylic acid and hydroxylalkyl acrylate, which cannot be used in the practice of the invention.

Neither the '613 disclosure nor the '760 disclosure suggests the claimed invention. The examiner's argument that applicants' "comprising" claim language permits the presence of functional monomer and crosslinker is inappropriate since the claims specifically recite that these components cannot by present.

Applicants submit that the claimed invention would not be obvious from the '613 disclosure or the '760 disclosure. Withdrawal of the Section 103 rejections based on '613 and '760 is requested.

Favorable reconsideration and the allowance of claims 1-14 is solicited.

Respectfully submitted,



November 21, 2003

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